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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/806,952 | 04/05/2001 | Olivier Lavergne | 427.046 | 9561 |

7590 06/27/2003

Bierman Muserlian and Lucas
600 Third Avenue
New York, NY 10016

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| EXAMINER |
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DESAI, RITA J

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| ART UNIT | PAPER NUMBER |
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1625

DATE MAILED: 06/27/2003

124

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,952

Applicant(s)

LAVERGNE ET AL.

Examiner

RITA J. DESAI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/12/03.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5, 24, 26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5, 24, 26 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Continued Prosecution Application

The request filed on 6/12/03 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/806952 is acceptable and a CPA has been established. An action on the CPA follows.

The claims pending are 5, 24,26 and 27.

The rejection of claim 26 under 35 USC 112 has been withdrawn since applicants have amended it.

The claims 4,5,24 and 26 rejection under 35 USC 102 e and 103 over Curran '832 has not been withdrawn since applicants have not perfected their priority. An English translation is required.

The rejection claims 4,5 24 and 26 rejection under 35 USC 102 e and 102b and 103 over Biggs 876 has been withdrawn since applicants have amended the claims and deleted other substitutents.

Claim Rejections - 35 USC § 103

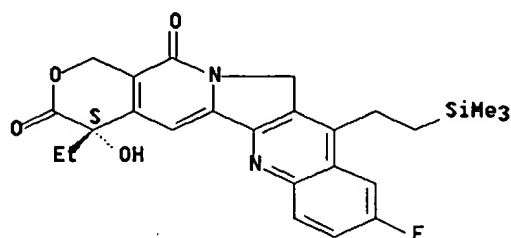
Claims 5, 24, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauseer WO 98/07727 in combination with Journal of Medicine Oliver Lavergne et al 1998 (cited in the 1449 filed 4/5/2001).

Applicants compounds are homocamptothecins (analogs of camptothecin, the ring with Oxygen is 7 membered ring , also called hcamptothecin or hCPT) with its R6 having a Si containing substituent.

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Scope and Content of Prior Art MPEP 2141.01

WO 98/07727 teaches the camptothecins of the formula



These are camptothecins wherein the applicants R2, R3 or R4 are hydrogen or a halogen and R5 is a Si containing group.

The reference teaches that the presence of the Si containing group at that position makes them highly lipophylic.

Oliver Lavergne et al discloses and teaches that CPT and its analog hCPT show and exhibit the same properties. See whole document specifically page 5413 . The reference specifically teaches that the hCPT is more effective and efficacious giving an impressive tumor growth delay see table 3 on page 5414. The data demonstrate that hCPT provides a valuable template for the preparation of new Topo I inhibitors with a high cytotoxicity towards tumor cell lines. Thus making hCPT a promising anticancer agent.

Thus teaching that CPT and hCPT are both valuable as anticancer agents.

Difference Between the Prior Art and the Claims MPEP 2141.02

Hauseer's compounds are highly lipophylic Si group containing camptothecins and not the hcamptothecins as in the instant invention.

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Prima Facie Obviousness Rational and Motivation MPEP 2142-2143

Oliver Lavergne et al teaches that hcamptothecins is more effective and efficacious in tumor growth delay, thus making hCPT a promising new cancer agent. Hauseer teaches that Si containing groups make the CPT more lipophylic and hence more effective.

Motivation comes from the Hauseer reference which show that the Si containing CPT compounds are highly lipophylic and more effective than the water soluble CPT or hCPT as it enhances tissue penetration and bioavailibility .

Thus one of skill in the art would be motivated to put a Si containing substituent on the hCPT to make it hightly lipophylic and hence more effective since Lavergne teaches that hCPT is also or even more so a cancer treating agent.

Conclusion

The pending claims 5,24,26 and 27 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RITA J. DESAI whose telephone number is 703-305-1868. The examiner can normally be reached on Monday - Friday,9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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R.D. Desai

R.D.

JUNE 24, 2003